

K1004174

510(K) Summary

Submitter: QuickLase Limited
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MAR 1 6 2010

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Preparation Date: February 9, 2010

Device Trade Name: QuickLase™DUAL+ Dental Laser
QuickLase™ (810nm) Dental Lasers
QuickLase™ (980nm) Dental Lasers

Common Name: Dental Diode Laser

Classification Name: Instrument, surgical, powered, laser

Regulation Description: 878.4810 Laser surgical instrument for use in general and plastic surgery and dermatology
A. Identification.
(1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide
(2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.
B. Classification
(1) Class II

Product Code: GEX

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Device Class	2
Review Panel	General & Plastic Surgery
Equivalent Device:	TwinWave and TidalWave by Lumen Development and Manufacturing, Inc., a California Corporation, K072295

AND

DioDent Micro 980/810 by Hoya Conio, Inc, K063384
Odyssey Navigator Diode Laser by Ivoclar Vivadent Inc, K062258
SIROLaser by Sriona Dental Systems, GmbH, K053161
LaserSmile by BioLase Technology, Inc., K030539

Device Description:	<p>The laser source of the QuickLase™DUALDental Lasers or QuickLase™810/980 Dental Laser is an array of Gallium Aluminum Arsenide (GaAlAs), solid state, semiconductor diode lasers. The individual lasers comprising the array are capable of producing invisible infrared laser energy at either 810 or 980 nanometers depending upon the concentration of and construction of the epitaxial layers of the diode. The delivery system consists of a fiber optic cable with a nominal diameter of 400 microns. In all available configurations, that portion of the delivery system that is handled by the operator and/or in contact with the patient can be sterilized by heat, steam, gas, chemicals or combinations thereof. Activation of the laser occurs after the operator either selects or enters the parameters for the procedure, verifies and authorizes the parameters and depresses a footswitch which fires the laser. The footswitch is an on/off switch. The interface for input is electro-mechanical by way of a membrane switch pad. The laser operates in continuous wave or pulse mode which is selected and/or verified by the operator. A visible aiming beam is provided in the form of a visible red laser which emits not more than 5mW (user adjustable and verified) in the 640-650 nanometer wavelength range.</p>
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Intended Use:	<p>The QuickLase™DUALand QuickLase™810/980 Dental Lasers are intended for incision, excision, ablation, vaporization, and/or coagulation of oral soft tissues (including marginal and interdental gingival and epithelial lining of free gingiva). It is also intended for light activation</p>
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for bleaching materials for teeth whitening, and laser assisted bleaching/whitening for teeth whitening.

Comparison:

The QuickLaseDUAL, QuickLase810, and QuickLase980, Diode Dental Laser Systems in their various configurations are, in fact, the TwinWave, TidalWave810, and TidalWave980 Diode Dental Lasers Systems that were cleared by the FDA on December 18, 2007 under 510(K) Number: K072995. The applications having been submitted by Lumen Development and Manufacturing, Inc. a California Corporation. We, QuickLase Limited, entered into a joint development agreement for these devices and, by the terms of the contract, were given rights in Europe. We obtained CE testing and marking and launched these lasers under the tradename QuickLaseDUAL+, QuickLase810, and QuickLase980. These lasers have performed flawlessly in Europe in thousands of procedures over the past 2 years. Lumen Development and Manufacturing, Inc., a California Corporation, fell under hard times and is out of business. According to the terms in our contract we are now able to market the devices in the USA. We are, therefore, applying for 510(K) clearance from the FDA for marketing the devices in the USA. With a notable caveat; these lasers are not substantially equivalent to, they are identical in terms of safety and efficacy. The only difference between the approved devices under 510(K) number K072995 and the devices covered in this application are the brandname change from TwinWave, TidalWave 810, and TidalWave980 to, QuickLaseDUAL+, QuickLase810, and QuickLase980 respectively, and some cosmetic differences in the housings. The units operate exactly the same and produce exactly the same results.

None the less, we offer the exact same narrative in this Summary as was submitted in and cleared in 510(k) Number K072995:

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The QuickLase™DUALDental Laser produces a power range of .1-5 Watts of 980nanometer laser energy and .1-5watts of 810nanometer laser energy; a combination of .1-10watt of invisible infrared energy. The QuickLase™810/980 980 Dental Laser produces a power range of .1-10 Watts of 980nanometer invisible infrared energy. The QuickLase™810/980 810 Dental Laser produces a power range of .1-10 Watts of 810nanometer invisible infrared energy. An operator adjustable visible red aiming beam is incorporated by way of solid state 640-650nanometer range solid state lasers with a maximum output of 5 milliwatts. The energy is delivered through 400 micron diameter optical fiber. All four of the comparable devices deliver comparable energy density through identical or similar/comparable fiber delivery systems; therapeutic results are identical. The SiroLaser and DioDent Micro 980 are rated at 7 and 3watts (respectively) of 980nanometer laser energy. The LaserSmile and Navigator are rated at 10 and 3 watts (respectively) of 810nanometer laser energy. All comparable devices have aiming beams and similar physical specifications. All devices share similar methods of control, safety features and performance monitoring.

Performance Standards: The device complies with the performance requirements of 21 CFR 1040.10 and 1040.11, with permissible deviations relative to Laser Notice 50, Dated July 26, 2001. The device has been tested by Notified Body and are CE mark and thereby complies with other international standards including IEC 60601 and 13485 Standards.

Clinical Performance: None

Non-Clinical Performance: Tests confirm that the power densities for treatment are identical in all devices insuring that all devices provide the exact same efficacy. Similar power density and safety controls insure equivalent or superior safety performance to the comparison device. Please see attached data summary.

Additional Information: None requested at this time.

Conclusions: The QuickLase™DUAL Dental Laser or The QuickLase™810/980 Dental Laser are, in terms of Safety and Efficacy, exactly the same as the TwinWave and TidalWave devices cleared in 510(K) number K072295 and

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are only different in Brandname and certain cosmetic differences in the housings. Additionally, the QuickLase™DUAL Dental Laser or The QuickLase™810/980 Dental Laser are substantially equivalent to the listed devices without raising any issues of safety or efficacy. The device shares similar intended uses, and similar functional and performance characteristics. The device is designed to and its components have been evaluated and/or tested to comply with or exceed relevant federal safety and performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

MAR 16 2010

QuickLase Limited
% QuickLase - Engineering and Regulatory Consulting
Mr. Calvin Ostler
P.O. Box 1264, 1094 West Greasewood Drive
Riverton, Utah 84065

Re: K100474

Trade/Device Name: QuickLase™ DUAL+ Dental Laser
QuickLase™ (810nm) Dental Lasers
QuickLase™ (980nm) Dental Lasers

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
Plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: February 27, 2010

Received: March 09, 2010

Dear Mr. Ostler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

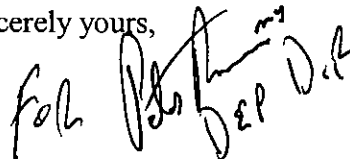
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K100474

Device Name: QuickLase™DUAL+ Dental Laser, QuickLase™ 810 Dental Lasers,
QuickLase™ 980 Dental Lasers

Indications for Use: For the incision, excision, ablation, vaporization, hemostasis, and treatment of oral soft tissue.

Examples:

Excisional and incisional biopsies	Frenectomy and Frenotomy
Exposure of unerupted teeth	Gingival Troughing for crown impressions
Fibroma removal	Gingivectomy
Gingivoplasty	Gingival incision and excision
Hemostasis and coagulation	Implant Recovery
Incision and drainage of abscess	Leukoplakia
Operculectomy	Oral papillectomies
Pulpotomy	Pulpotomy as an adjunct to root canal therapy
Reduction of gingival hypertrophy	Reduction of bacterial level (decontamination) and inflammation
Soft Tissue crown lengthening	Treatment of aphthous ulcers
Vestibuloplasty	Lesion (tumor) removal
Laser Soft Tissue Curettage	Treatment of canker sores, herpetic and other ulcers of the oral mucosa
Tissue Retraction	

Removal of Diseased, Infected, Inflamed and necrotic soft tissue within the periodontal pocket
Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
Sulcular debridement (removal of necrotic, diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility
Light activation of bleaching materials for teeth whitening
Laser-assisted whitening/bleaching of teeth

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (Division Sign-Off)

Neil P. [Signature] Farman
Division of Surgical, Orthopedic,
and Restorative Devices

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510(k) Number K100474

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